

Article - Health - General

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§21–218.

(a) In this section, “antibiotic drug” means any drug that:

- (1) Is intended for use by a human being;
- (2) Contains any quantity of a chemical substance or the chemically synthesized equivalent of a chemical substance that is produced by microorganisms; and
- (3) Can inhibit or destroy microorganisms in dilute solution.

(b) In addition to any other ground that may apply under § 21-217 or § 21-220 of this subtitle, a drug is misbranded if:

(1) It is for use by a human being and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca leaves, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, sulphonmethane, or any chemical derivative of any of these substances, which derivative, after investigation, has been designated as habit forming under a rule or regulation adopted under the federal act or by the Secretary under this subtitle, unless its label states the name and quantity or proportion of the substance or derivative and, immediately beside that information, a warning that states: “Warning -- May be habit forming.”;

(2) It has an established name and, to the exclusion of any other nonproprietary name except the applicable systematic chemical name or the chemical formula of the drug, its label does not bear the established name of the drug;

(3) Except as otherwise permitted by a rule or regulation adopted under the federal act or by the Secretary under subsection (d)(2) of this section, it is made from 2 or more ingredients and its label does not bear the established name, if any, of and the quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any of these substances, but a nonprescription drug is not misbranded under this item on the ground that its label does not show the

quantity or proportion of an active ingredient unless the ingredient is specifically named in this item;

(4) Except as otherwise permitted by a rule or regulation adopted under the federal act or by the Secretary under subsection (d)(2) of this section, it is a prescription drug, and the established name of the drug and any of its ingredients are not:

(i) Printed prominently on the label of the drug in type at least half as large as that used to print any proprietary name or other designation of the drug or of its ingredients; and

(ii) Printed in this same manner on any labeling of the drug on which any name for the drug or for an ingredient is used;

(5) It purports to be a drug whose name is recognized in an official compendium and it is not:

(i) Labeled as required by the applicable official compendium;
or

(ii) Packaged as required by:

1. The applicable official compendium; or
2. A consent order granted under the federal act or by the Secretary to modify the packaging requirements of the official compendium;

(6) It has been found under the federal act or by the Secretary to be a drug liable to deterioration, and:

(i) It is not packaged in the form and manner required by the rules and regulations adopted under the federal act or by the Secretary; or

(ii) Its label does not bear a statement of precautions as required by those rules and regulations;

(7) It is a prescription drug that was manufactured after July 1, 1976 and its label does not bear the name of the actual manufacturer of the drug;

(8) Its container is made, formed, or filled in a manner that is misleading;

(9) It is an imitation of another drug;

(10) It is offered for sale under the name of another drug;

(11) It is or it is purported to be a drug that is composed in whole or in part of insulin and it is not from a batch for which a currently unexpired certificate or release has been issued under the federal act;

(12) It is or it is purported to be a drug composed in whole or in part of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or of any derivative of these drugs and, unless the drug has been exempted by rules and regulations adopted under the federal act, it is not from a batch for which a currently unexpired certificate or release has been issued under the federal act;

(13) It is a color additive that is intended to be used in or on a drug for the purpose of coloring only and its packaging or labeling does not conform to any requirement adopted under § 21-239 of this subtitle; or

(14) It is a prescription drug that is distributed or offered for sale in this State, and the manufacturer, packer, or distributor of the drug does not include in any advertisement, or in any other descriptive printed matter that it issues or causes to be issued regarding the drug, a true statement of:

(i) The established name of the drug, which name is printed prominently and in type at least half as large as that used for any printed trade or brand name of the drug;

(ii) The formula of the drug showing quantitatively each ingredient of the drug to the extent required for labels under the federal act; and

(iii) A brief summary of any other information that relates to the side effects, contraindications, or effectiveness of the drug, as is required by the rules and regulations adopted under the federal act.

(c) (1) For purposes of subsection (b)(5) of this section, which imposes packaging and labeling requirements on any drug that is purported to be recognized in an official compendium, the provisions of this subsection shall apply.

(2) (i) Except as otherwise provided in this subsection, if the drug is recognized in both the United States Pharmacopoeia and National Formulary and in the Homeopathic Pharmacopoeia of the United States, it is subject to the packaging and labeling requirements of the United States Pharmacopoeia and National Formulary.

(ii) If the drug is labeled and offered for sale as a homeopathic drug, it is subject to the packaging and labeling requirements of the Homeopathic Pharmacopoeia of the United States and not to the requirements of the United States Pharmacopoeia and National Formulary.

(3) If there is an inconsistency between the provisions of paragraph (2) of this subsection and the requirements of subsection (b)(2), (3), or (4) of this section as to the name by which a drug or its ingredients shall be designated, the requirements of subsection (b)(2), (3), or (4) of this section control.

(d) (1) For purposes of subsection (b)(1) of this section, after investigation, the Secretary may adopt a rule or regulation that designates any chemical derivative of any substance named in that subsection as habit forming.

(2) If, as to a particular drug, compliance with any requirement of subsection (b)(3) or (4) of this section is impractical, the Secretary shall adopt a rule or regulation that, to the extent appropriate, exempts the drug from the provisions of those subsections.

(3) (i) If the Secretary finds that a drug is liable to deterioration, the Secretary may adopt a rule or regulation that specifies how the drug is to be packaged and requires that its label bear a statement of precautions.

(ii) The Secretary may not adopt a rule or regulation under subparagraph (i) of this paragraph before the Secretary has informed the appropriate body that is charged with the revision of the official compendium of the need for the packaging or labeling requirements and that body has failed to adopt the requirements within a reasonable time.

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